IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

PLANNED PARENTHOOD OF THE HEARTLAND,)
Plaintiff,))
V.)
DAVE HEINEMAN, Governor of Nebraska, in his official capacity;) Case No. 4:10-cv-3122
JON BRUNING, Attorney General of Nebraska; in his official capacity;)))
KERRY WINTERER, Chief Executive Officer, and DR. JOANN SCHAEFER, Director of the Division of Public Health, Nebraska Department of Health and Human Services, in their official capacities; and)))))
CRYSTAL HIGGINS, President, Nebraska Board of Nursing, and BRENDA BERGMAN-EVANS, President, Nebraska Board of Advanced Practice Registered Nurses, in their official capacities;))))
Defendants.)) _)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION AND TEMPORARY RESTRAINING ORDER

Plaintiff Planned Parenthood of the Heartland ("Planned Parenthood") seeks a preliminary injunction and, if necessary to preserve the status quo pending the determination of its motion for a preliminary injunction, a temporary restraining order, against enforcement of L.B. 594, 101st Leg. Reg. Sess. (Neb. 2010), to be codified within Neb. Rev. Stat. §§ 28-325, 28-340, 38-2021, 28-101, 28-326, 28-327, 28-327.01, 28-327.03, 28-327.04 ("Act") (attached as Ex. 1 to the Index of Evidence). The Act is scheduled to take effect on July 15, 2010. The Act

imposes so-called "informed consent" requirements on abortion providers which at first blush may appear to be straightforward and scientific. Upon closer examination, however, it is clear that the requirements are not only a drastic departure from accepted medical practice, but literally impossible for any provider to satisfy.

Read literally, the Act requires Planned Parenthood, and all other providers of abortion services, prior to performing an abortion, to:

- (1) identify, retrieve, and review thousands of articles—dating back more than a century, in dozens of different languages, and appearing in any of thousands of worldwide journals—for information related to so-called "risk factors" and "complications" associated with abortion as those terms are broadly defined in the Act;
- (2) evaluate every patient for the infinite list of "risk factors" culled from this enormous body of literature and inform the patient of the results of the evaluation in writing; and
- (3) disclose an equally vast list of "complications" associated with those risk factors and the quantifiable "risk rates," if any.

See Act, §§ 4(4)-(5). The Act requires Planned Parenthood to conduct these evaluations and make these disclosures without regard to the validity of the findings in the articles and without regard to whether the information is applicable and material to Planned Parenthood's patients.

Because the Act imposes impossible requirements on Planned Parenthood prior to performing an abortion, if taken literally, the Act effectively bans abortions in the State of Nebraska. To the extent the Act incorporates any reasonable limitations on what is required, those limitations are wholly unclear, and, therefore, the Act is impermissibly vague. In addition, the Act requires Planned Parenthood to give untruthful, misleading, and not relevant information

to its patients in violation of the First and Fourteenth Amendments. Finally, the Act's application to out-of-state providers violates the Due Process Clause and the Commerce Clause. For any of these reasons, the Act is unconstitutional and cannot stand.

Moreover, if the Act takes effect, it will irreparably harm Planned Parenthood and its patients by either denying women the opportunity to terminate their pregnancies or putting Planned Parenthood and its staff at risk of licensing penalties, including revocation of Planned Parenthood's license to operate its health care facility in Lincoln and its staff's professional licenses; significant civil penalties, including damages for wrongful death and professional negligence, costs, and attorneys' fees; substantial financial harm; and ongoing violations of their constitutional rights and those of their patients. A preliminary injunction and, if necessary, a temporary restraining order, to prevent the Act from going into effect are therefore warranted.

STATUTORY FRAMEWORK

Under Nebraska law, "no abortion shall be performed except with the voluntary and informed consent of the woman upon whom the abortion is to be performed." Neb. Rev. Stat. § 28-327. The Act provides that "[e]xcept in the case of an emergency situation, consent to an abortion is voluntary and informed only if," among other things, "a physician, psychiatrist, psychologist, mental health practitioner, physician assistant, registered nurse, or social worker licensed under the Uniform Credentialing Act," has, among other things, "[e]valuated the pregnant woman to identify the presence of any risk factors associated with abortion." Act, § 4(4)(a). After the evaluation, the licensed person must "[i]nform[] the pregnant woman and the physician who is to perform the abortion of the results of the evaluation in writing." Id. § 4(4)(c). The written evaluation shall include "both the licensed person's written certification and the woman's written certification that the pregnant woman was informed of the risk factors

associated with abortion as discussed." <u>Id.</u> In addition, "[i]f any risk factors associated with abortion were identified" the patient must be informed of "[e]ach complication associated with each identified risk factor" and "[a]ny quantifiable risk rates whenever such relevant data exists" "in such manner and detail that a reasonable person would consider material to a decision of undergoing an elective medical procedure." <u>Id.</u> § 4(5).

A "[r]isk factor associated with abortion" is defined as

any factor, including any physical, psychological, emotional, demographic, or situational factor, for which there is a statistical association with one or more complications associated with abortion such that there is less than a five percent probability (P < .05) that such statistical association is due to chance. Such information on risk factors shall have been published in any peer-reviewed journals indexed by the United States National Library of Medicine's search services (PubMed or MEDLINE) or in any journal included in the Thomson Reuters Scientific Master Journal List not less than twelve months prior to the day preabortion screening was provided.

<u>Id.</u> § 3(11). "Complications associated with abortion" is defined as "any adverse physical, psychological, or emotional reaction that is reported in a peer-reviewed journal to be statistically associated with abortion such that there is less than a five percent probability (P < .05) that the result is due to chance." <u>Id.</u> § 3(2).

The Act further provides that "any physician advertising services in this state shall be deemed to be transacting business in this state pursuant to section 25-536 and shall be subject to the provisions of section 28-327." <u>Id.</u> § 10(4).

The Act imposes significant civil penalties on Planned Parenthood if it fails to comply with any of its requirements. Indeed, if Planned Parenthood misses even one of the potentially hundreds, if not thousands, of "risk factors," associated "complications," and/or quantified "risk rates" mentioned in the vast universe of literature covered by the Act, it could be liable for damages for the wrongful death of the embryo or fetus, even without a showing by the plaintiff

that she suffered the complication about which the physician allegedly failed to warn her, as well as for professional negligence, and for costs and attorney's fees. <u>Id.</u> §§ 7, 6, 10. The Act creates a presumption that the woman would not have had the abortion if the physician had complied with the Act's requirements, <u>id.</u> § 10(1), and allows recovery for pain, emotional distress, and related injuries without any showing of physical injury, <u>id.</u> § 10(2).

Further, a health care facility where abortions are performed in violation of the Act faces licensing penalties, including fines, suspension and/or revocation of its license to operate. See Neb. Rev. Stat. §§ 71-448 to 449; 175 Neb. Admin. Code § 7-006.

Finally, a health care professional other than a physician—including a registered nurse or a nurse practitioner—who assists in the performance of abortions in violation of the Act may face professional discipline, including license suspension or revocation. <u>See</u> Neb. Rev. Stat. §§ 38-178 to 179, 196.

Independently of the passage of the Act, Nebraska statutory law (in addition to the common law) already requires informed consent for abortions. The Act supplements those informed consent requirements, which state that "[n]o abortion shall be performed except with the voluntary and informed consent of the woman upon whom the abortion is to be performed," id. § 28-327, and require, among other things, that the patient be told "[t]he particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, perforated uterus, danger to subsequent pregnancies, and infertility" and "[t]he medical risks associated with carrying her child to term." Id. §§ 28-327(1)(a), (c). The existing informed consent law also requires that a patient be told prior to the abortion "that she cannot be forced or required by anyone to have an abortion and is free to withhold or withdraw her consent for an abortion." Id. § 28-327(1)(d).

STATEMENT OF FACTS

A. Planned Parenthood and Abortion Services in Nebraska

Planned Parenthood operates a health center in Lincoln, Nebraska, which provides a broad range of reproductive health services, including abortion. Declaration of Penelope A. Dickey ("Dickey Decl.") ¶ 4 (attached as Ex. 2 to the Index of Evidence). Planned Parenthood's Lincoln health center is licensed by the Department of Health and Human Services ("DHHS"). It is the only generally available provider of abortion services in Lincoln, and one of only two generally available abortion providers in the state. Id. ¶ 5. Before an abortion, as with any medical procedure, Planned Parenthood takes a number of steps to ensure that informed consent is obtained, including meeting all common and statutory law requirements, and ensuring that the woman is firm in her decision and was not coerced or pressured. Id. ¶ 7. Registered nurses and nurse practitioners, who are also licensed by DHHS, often assist the physician with performing abortion procedures at the Lincoln health center. Id. ¶ 8. Planned Parenthood also provides abortion services in Iowa and advertises those services in Nebraska. Id. ¶ 9.

B. Standard Informed Consent Practice

The Act's requirements dramatically depart from the professionally accepted standard for informed consent: to enable the patient to make meaningful decisions about his or her medical care by providing the patient with the information that is likely to be material to those decisions. Declaration of Paul S. Appelbaum, M.D. ("Appelbaum Decl.") ¶ 17 (attached as Ex. 3 to the Index of Evidence); Declaration of Darla Eisenhauer, M.D. ("Eisenhauer Decl.") ¶ 15 (attached as Ex. 4 to the Index of Evidence).

In order to accomplish that goal, selectivity is key, as patients who receive too much information are likely to become "flooded" and no longer process the information in any

meaningful way, thus damaging their ability to make informed medical decisions. Appelbaum Decl. ¶¶ 31-34; Eisenhauer Decl. ¶¶ 13. Thus, physicians develop general knowledge of and familiarity with the significant risks and benefits of the medical treatment or procedure being considered, as well as risk factors that would, if present, significantly change those risks and benefits. Appelbaum Decl. ¶¶ 18; Eisenhauer Decl. ¶¶ 12. This does not mean being aware of, much less disclosing, every potential complication or risk factor of the treatment or procedure that has ever been discussed in the medical literature. Rather, the physician's obligation is to develop general knowledge of and familiarity with the *significant* potential complications of the treatment or procedure being considered, as determined by some combination of the complication's frequency and its severity, Appelbaum Decl. ¶¶ 18-21; Eisenhauer Decl. ¶¶ 12, as well as the risk factors that, if present, would change the information the physician would give the patient about potential complications. Appelbaum Decl. ¶¶ 18; Eisenhauer Decl. ¶¶ 12.

Physicians focus on significant complications and risk factors because they are likely to be material to the patient—that is, relevant to the patient in making a meaningfully informed medical decision. Appelbaum Decl. ¶ 21; Eisenhauer Decl. ¶ 12. Exercising medical judgment to determine which information is likely to be material to the patient is an essential part of the physician's role. Appelbaum Decl. ¶ 21; Eisenhauer Decl. ¶ 13.

In contrast to the requirements of the Act, physicians do not develop their knowledge of complications and risk factors by doing a literature survey of every article ever published in a peer-reviewed journal on the treatments or procedures they provide. Rather, in typical practice, physicians develop this knowledge and familiarity from a variety of sources that synthesize and digest the information in the medical literature, including publications, committee opinions, and practice guidelines from professional organizations; review articles in major medical journals;

presentations at medical associations and continuing medical education meetings; and conversations with other physicians about their practices. Appelbaum Decl. ¶¶ 22-23; Eisenhauer Decl. ¶¶ 10-11. This allows physicians to stay informed about developments in their areas of practice, as well as to rely appropriately on the judgment of those with expertise in study methodology and statistical analysis. Appelbaum Decl. ¶¶ 24-27; Eisenhauer Decl. ¶¶ 10-11.

C. Impossibility of Complying with the Act's Requirements

Read literally, it is impossible to comply with the Act's requirements. See Declaration of Kelly Blanchard ("Blanchard Decl.") ¶¶ 12-31 (attached as Ex. 5 to the Index of Evidence); Dickey Decl. ¶ 11; Eisenhauer Decl. ¶¶ 6-9; Declaration of Jill L. Meadows, M.D. ("Meadows Decl.") ¶ 9 (attached as Ex. 6 to the Index of Evidence). PubMed/MEDLINE is an online, searchable database of approximately 20 million journal article citations. Blanchard Decl. ¶ 12. The Thomson Reuters Master Journal List ("MJL") is a list of approximately 16,500 journal titles, and some of the article citations published in the journals included on the MJL can be searched electronically using a search engine called "Web of Science." Id. ¶ 13. It is impossible to search every article ever published in any of the journals included on PubMed/MEDLINE or in the MJL through PubMed/MEDLINE or Web of Science. Id. ¶ 15. Second, of the articles that can be searched electronically through PubMed/MEDLINE or Web of Science, there is no way to electronically search the full text of those articles and, thus, even the broadest search would not yield every responsive article. <u>Id.</u> ¶¶ 17-21. Third, even if these limitations did not exist, it would be impossible to craft a search to comply with the Act that is both comprehensive and efficient in retrieving responsive articles. Id. ¶¶ 22-24. There are many additional limitations related to searching PubMed/MEDLINE and the MJL, including the fact that the MJL is routinely updated with potentially responsive materials, but users cannot easily access

information about which journals have been recently added or deleted; many of the potentially responsive articles on PubMed/MEDLINE and Web of Science could be in any of multiple foreign languages; and merely to retrieve articles that may contain responsive information could cost Planned Parenthood an exorbitant amount of money. Id. ¶¶ 25-27. Finally, even a review of only a few articles that are potentially responsive makes clear that it would be impossible for Planned Parenthood to evaluate patients for every risk factor and disclose every associated complication and quantified risk rate described in the literature covered by the Act. Id. ¶¶ 28-32.

D. Vagueness of the Act's Requirements

If there are certain implicit limitations on the Act's requirements, it is completely unclear what those are. Dickey Decl. ¶ 12; Meadows Decl. ¶ 10. For example, Planned Parenthood does not know whether there are any limits on the materials that must be searched or whether providers can use their medical judgment to determine what information must be included in the patient evaluation and discussion. Dickey Decl. ¶¶ 12-14; Meadows Decl. ¶¶ 10-13.

E. Untruthful, Misleading, and Not Relevant Information Required by the Act

Read literally, the Act will require Planned Parenthood to provide information to patients that is not true and/or is misleading, and is not in any way relevant to the patient's medical decision-making. Meadows Decl. ¶¶ 14-38; Appelbaum Decl. ¶¶ 35-43, 46-47. This includes (among other examples) information on supposed risk factors and complications that have been rejected by mainstream medicine, Meadows Decl. ¶¶ 16-21; Appelbaum Decl. ¶ 37, as well as risk factors and complications that were found only in methodologically flawed and unreliable studies, Meadows Decl. ¶¶ 16-21, 31-38; Appelbaum Decl. ¶¶ 44, 49-50, in studies of out-of-date medical practice and procedures, Meadows Decl. ¶¶ 26-30; Appelbaum Decl. ¶¶ 37-38, or

in studies in developing countries with vastly different medical and social contexts from those of patients receiving services in Nebraska, Meadows Decl. ¶¶ 22-25; Appelbaum Decl. ¶ 40.

F. Irreparable Harm

If the Act takes effect, Planned Parenthood will be faced with the choice of continuing to perform abortions, and thereby risking countless civil lawsuits, suspension or loss of its health care facility license and the professional licenses of its staff, significant financial harm, and ongoing violations of its constitutional rights and those of its staff and their patients, or ceasing to perform abortions, and depriving women of the ability to have an abortion in Nebraska.

Dickey Decl. ¶¶ 3, 15-16.

ARGUMENT

Planned Parenthood is entitled to a preliminary injunction and, if necessary, a temporary restraining order pending a determination on Planned Parenthood's motion for a preliminary injunction. In Planned Parenthood of Minnesota, North Dakota, South Dakota v. Rounds, 530 F.3d 724 (8th Cir. 2008) (en banc), the Eighth Circuit clarified the standard for preliminary injunctions established by the court in Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109 (8th Cir. 1981) (en banc) for enjoining legislative enactments. 530 F.3d at 731-32. The Court held that "where a preliminary injunction is sought to enjoin the implementation of a duly enacted state statute . . . district courts [must] make a threshold finding that a party is likely to prevail on the merits." Id. at 732-33. If the party "makes a threshold showing that it is likely to prevail on the merits, the district court should then proceed to weigh the other Dataphase factors," id. at 732, namely, (1) the threat of irreparable harm to plaintiff; (2) the state of balance between this harm and the injury that granting the injunction will inflict on defendants; and (3) the public interest, Dataphase, 640 F.2d at 114.

Planned Parenthood is exceedingly likely to prevail on the merits. Read literally, the Act imposes impossible requirements on providers and thus effectively bans abortions in violation of women's constitutional right to choose to terminate a pregnancy. To the extent there are any limitations on the Act's requirements, the law is void for vagueness because it is completely unclear what those limitations are. The Act also requires Planned Parenthood and its staff to give untruthful, misleading, and not relevant information to their patients in violation of providers' First Amendment and patients' Fourteenth Amendment rights. Finally, the Act's application to out-of-state providers violates the Due Process Clause and the Commerce Clause.

The remaining <u>Dataphase</u> factors are also present—Planned Parenthood will be irreparably harmed, and there is no injury to Defendants, nor benefit to the public interest, in enforcing an unconstitutional law. This Court should therefore temporarily enjoin the Act to preserve the status quo during the pendency of this litigation.

I. PLANNED PARENTHOOD WILL SUCCEED ON THE MERITS

A. The Act Violates Patients' Constitutional Right to Liberty Because It Imposes Impossible Requirements on Abortion Providers

The Act appears to condition the performance of a legal and constitutionally protected medical procedure, abortion, on abortion providers' compliance with unprecedented, impossible so-called "informed consent" requirements. Read this way, the Act effectively imposes a ban on abortion and thus violates patients' right to liberty protected by Due Process Clause of the Fourteenth Amendment because the only way for Planned Parenthood to comply with the Act is by refraining from providing abortions. Decisions surrounding abortion involve "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy," and "central to the liberty protected by the Fourteenth Amendment." Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833, 851 (1992). To protect the

woman's "constitutional liberty" in "retain[ing] the ultimate control over her destiny and her body," <u>id.</u> at 869, the Court in <u>Casey</u> repeatedly stated that a State may not impose a ban on previability abortion. <u>See id.</u> at 879 ("[A] State may not prohibit any woman from making the ultimate decision to terminate her pregnancy before viability."); <u>id.</u> at 846 ("Before viability, the State's interests are not strong enough to support a prohibition of abortion"); <u>id.</u> at 871 (state interest is "insufficient to justify a ban on abortions prior to viability"); <u>id.</u> ("The woman's right to terminate her pregnancy before viability is the most central principle of <u>Roe v. Wade</u>. It is a rule of law and a component of liberty we cannot renounce.").

The Act's requirements vastly depart from accepted medical practice and would be impossible for any provider to satisfy. See Blanchard Decl. ¶ 12-31; Dickey Decl. ¶ 11; Eisenhauer Decl. ¶ 6-9; Meadows Decl. ¶ 9. If the Act is taken literally, healthcare providers must identify, retrieve, and review every article in every peer-reviewed journal indexed by PubMed or MEDLINE or in any journal included in the Thomson Reuters Scientific Master Journal List ("MJL") that could trigger an evaluation and/or disclosure obligation because it could include information on a "risk factor" and "complication" as broadly defined in the Act; evaluate every patient for the resulting list of supposed "risk factors;" inform them of the results of that evaluation in writing, and disclose the associated "complications," as well as the quantifiable "risk rates," if any. This is simply impossible for at least the following reasons:

(1) the expansive definition of "risks factors" and "complications"

First, the Act appears to impose virtually no limitations on what "risk factors" and "complications" it covers. "Risk factors" is defined broadly to include "any factor," including, but not limited to, "any physical, psychological, emotional, demographic, or situational factor" for which there is a "statistical association" with "one or more complications associated with

abortion." Act, § 3(11) (emphasis added). Thus, "risk factors" appears to include any facet of the woman's life, and captures a range of factors that the mainstream medical literature would not necessarily identify as risk factors. Appelbaum Decl. ¶ 16; Blanchard Decl. ¶ 24. Similarly, "complications" is also defined broadly to include "any adverse physical, psychological, or emotional reaction," Act, § 3(2) (emphasis added), and thus arguably includes expected aftereffects of an abortion, or ones that are mild and transient, which would not be considered "complications" in conventional medical usage and thus not identified in the literature as such. Appelbaum Decl. ¶¶ 14-15; Blanchard Decl. ¶ 24.

The expansiveness of these definitions greatly increases the sheer volume of articles that would trigger evaluation and/or disclosure duties under the Act. Moreover, to the extent the definitions are not the same as conventional medical usage, they make it impossible to search for the full set of responsive articles in any feasible way.

- (2) impossibility of identifying all "risk factors" and "complications"
 - (a) the boundless volume of literature covered by the Act and the limitations on the ability to search that literature

The problem with the expansive definitions of "risk factors" and "complications" covered by the Act is compounded by the Act's inclusion of any risk factor and complication published in "any peer-reviewed journals indexed by the United States National Library of Medicine's search services (PubMed or MEDLINE)" or in "any journal included in the Thomson Reuters Scientific Master Journal List." Act, § 3(11) (emphases added). PubMed, an online, searchable database of biomedical journal article citations and abstracts maintained by the National Center for Biotechnology Information at the U.S. National Library of Medicine, contains approximately 20 million citations for articles in the biomedical literature from MEDLINE, life science journals, and online books. MEDLINE is the largest component of PubMed and contains over 18 million

article citations from approximately 5,400 worldwide journals in approximately 40 different languages. (As PubMed includes MEDLINE, we will refer hereafter only to "PubMed" when referring to the two databases.) Blanchard Decl. ¶ 12. The MJL is a list of approximately 16,500 journal titles created and maintained by Thomson Reuters. Thomson Reuters has a proprietary search engine called "Web of Science" that allows users to search electronically *some* of the article citations published in the journals included in the MJL. Id. ¶ 13. There are significant differences between the journals carried by PubMed and the MJL, as well as significant differences between the articles that can be searched electronically using PubMed and Web of Science. Id. ¶ 14.

(i) not all the articles contained in the journals included on PubMed and the MJL can be searched electronically through PubMed or Web of Science

The Act covers information on risk factors published in any peer-reviewed journal "indexed" by PubMed or "included" in the MJL, not only the articles from those journals that can be searched through the online search engines. Both PubMed and the MJL include many journals for which not all the articles ever published in those journals can be searched through PubMed or Web of Science. For example, PubMed and the MJL both include the "International Journal of Qualitative Studies on Health and Well-Being." That journal has been published since 2006, but only articles since 2009 can be accessed using PubMed or Web of Science. Even journals as prestigious and well-known as "The Lancet" are not fully accessible electronically through either PubMed or Web of Science. Id. ¶ 15. Thus, Planned Parenthood would not only have to figure out which articles from journals indexed by PubMed or included in the MJL are not searchable through the online search engines, but then also find some way to access and search those articles. There is no question that this alone would be an impossible task. Id. ¶ 16.

(ii) even those articles that are searchable through PubMed or Web of Science are only partially searchable

Even if every article published in every journal included on PubMed and the MJL could be searched electronically through PubMed or Web of Science, it would still be impossible to comply with the Act. Neither PubMed nor Web of Science can search the full text of each article (unlike, for example, Westlaw, which does so with respect to case law). Therefore, one cannot be sure that a search on PubMed or Web of Science will find all the articles that could trigger obligations under the Act.

Rather than searching full text, PubMed searches a series of fields, including article title, abstract, author, and "MeSH" (medical subject headings) terms. <u>Id.</u> ¶ 17. MeSH is the National Library of Medicine's controlled vocabulary thesaurus of terms used to describe the subject content of an article on MEDLINE. There are more than 25,000 descriptors (or terms) in MeSH, including "abortion, induced" which is defined as the "[i]ntentional removal of a fetus from the uterus by any of a number of techniques." MeSH terms are used only for those subjects that are substantially discussed as opposed to merely mentioned in an article. <u>Id.</u> ¶ 18. Not every journal article appearing on PubMed is assigned MeSH terms. <u>Id.</u> ¶ 19. Web of Science also searches a series of fields, including title, abstract, and keywords. <u>Id.</u> ¶ 20.

Thus, in either PubMed or Web of Science, unless the article contains the relevant search term or terms in one of the search fields, it would not turn up in a search. <u>Id.</u> For example, a search for "abortion" yields more than 66,000 and 30,000 results on PubMed and Web of Science, respectively, dating back to 1900. But even this incredibly broad search will not capture every responsive article. Of the articles that are not assigned MeSH terms on PubMed, an article that contains responsive information in the text, but does not use the term "abortion" in the title or abstract would not turn up. Of the articles assigned MeSH terms, an article that is

focused on miscarriage, for example, but that mentions some responsive information related to induced abortion, would also likely be missed because MeSH is only used for subjects that are discussed in an article as opposed to merely mentioned. And, on Web of Science, unless the term "abortion" is a keyword, an article containing responsive information may not turn up if "abortion" is not used in its title or abstract. Id. ¶ 21. Of course, even ignoring the fact that some responsive articles will be missed in a search for the term "abortion," it would be impossible to sort through more than 66,000 articles from PubMed and more than 30,000 articles from Web of Science. Id. But this is what the Act, if taken literally, requires, because if Planned Parenthood misses even one responsive "factor" mentioned anywhere—even in a footnote—in one article, it could be at risk of significant penalties.

(b) the impossibility of crafting a comprehensive search that efficiently retrieves responsive articles

Parenthood still would not be able to comply with the Act because it is impossible to craft a comprehensive search that efficiently retrieves responsive articles. For example, even a search for (1) "induced abortion" (including the MeSH term "abortion, induced" and one synonym sometimes used to describe induced abortions, "elective abortion") and (2) the term "risk factors" or "complications" or any of various potential synonyms of those terms, or other terms that may capture responsive information (including "counseling" or "informed consent") yields more than 19,000 results dating back to 1950 on PubMed alone. Id. ¶ 22. To determine which of these results contain potentially relevant information, Planned Parenthood would first have to sort through the titles of the articles and then the abstracts, where available. Looking at only the titles and abstracts, where available, of a random sample of 100 of these articles, a conservative estimate demonstrates that approximately 35-40 appear as though they may contain responsive

information. <u>Id.</u> ¶ 23. Thus, not including the additional results from Web of Science, Planned Parenthood would have to retrieve and review, at a minimum, almost 7,000 articles (35% of 19,000) to determine if they contain information that would trigger an obligation under the Act. <u>Id.</u>

And even this search would not yield every responsive article. Searching only for "induced abortion" eliminates some potentially responsive results because an article may refer instead to "pregnancy termination," "termination of pregnancy," or another synonym for "induced abortion." In addition, because "risk factors" and "complications" are defined so broadly in the Act, they include matters that would not necessarily be identified in the literature using these terms or their synonyms. Also, there are other synonyms for "risk factors" and "complications" and other terms that could capture additional responsive material under the Act that were not included in the above-described search. Indeed, an article that discusses a particular condition or risk factor—such as age, for example—might not use the general description "risk factor." Accordingly, it is impossible to craft a search that would both assure Planned Parenthood that all responsive articles have been captured and efficiently retrieve responsive articles. Id. ¶ 24.

(c) additional limitations

The impossibility of dealing with the infinite amount of materials that searching PubMed or the MJL would yield is exacerbated by a number of other problems, each of which is independently sufficient to make literal compliance with the Act an impossibility. First, journals are added and deleted from the MJL as often as every few weeks, but users cannot easily access information on which journals have been added or deleted. Journals that have been added may include ones that have been in publication for more than a year, and, thus, under the Act, could

contain articles that would immediately trigger evaluation and/or disclosure obligations. Act, §3(11) (requiring the information to "have been published . . . not less than twelve months prior to the day preabortion screening was provided"). Thus, Planned Parenthood would constantly have to search the MJL to determine if articles containing potentially relevant information had been added. If they had, and if those articles could not be retrieved quickly, even if Planned Parenthood could otherwise comply with the Act, it would have to postpone abortion procedures until the articles could be retrieved, reviewed, and any relevant information added to the patient evaluation and disclosures. Blanchard Decl. ¶ 25. If taken literally, this alone could prove so disruptive to Planned Parenthood's abortion services that it could not practically continue to operate.

Second, many articles on PubMed that may contain responsive information are in one of approximately forty different foreign languages. Only the title and sometimes the abstract (where the abstract is available) are translated into English. For example, PubMed contains a Chinese-language article entitled: "Postabortion complications and recovery of ovarian function in nulliparous women" that appears likely to be responsive under the Act. But without being able to read and analyze the article itself, it is impossible to determine whether it is responsive and, if it is, what information in the article should be disclosed. Id. \$\quantle 26\$. Web of Science also covers many journals that publish only their bibliographic information in English with full text in another language. Id. It would obviously be impossible for Planned Parenthood to review the potentially hundreds of foreign language articles that may contain information required by the Act.

Third, it would be impossible to access all the articles that result from searching PubMed or Web of Science. Many of the articles are not available online and would need to be sought

from libraries, publishers or other sources, in some cases for a fee. Of the articles available online, many are not available for free and typically cost \$25 or \$30 per article. In addition, Web of Science is marketed to large universities or institutions, and Thomson Reuters charges an annual fee in the tens of thousands of dollars to use this service. Thus, it could cost Planned Parenthood an exorbitant amount of money just to retrieve the articles that may contain responsive information. <u>Id.</u> ¶ 27. This cost would be prohibitive.

(3) impossibility of complying with the evaluation and disclosure obligations Even if all the responsive information could be gathered and reviewed, providers could never adequately meet the Act's evaluation and disclosure requirements. Review of even a small number of potentially responsive articles reveals that many studies that may appear to address the same risk factor are actually addressing fairly different risk factors using different approaches. For example, close scrutiny of three different studies addressing risk factors that could be characterized as broadly falling under the heading "ambivalence" reveal that they in fact address different risk factors evaluated using different methods and timing—including "moderate to severe" ambivalence toward abortion as determined in a psychiatric evaluation before the abortion was scheduled; whether the patient reported in a post-abortion interview that she had decided on abortion as soon as she discovered she was pregnant; and a woman's reported "satisfaction with the decision to end the pregnancy" based on a four-point scale in an interview conducted immediately before the abortion. <u>Id.</u> ¶ 28 (citing multiple studies). Further, each risk factor is associated with a different complication or complications—such as depression and guilt, "some kind of emotional distress," and "unfavourable emotional reactions" (including feeling unhappy, guilty, and resentful) occurring at different times—including as soon as two to three weeks after the abortion and up to one year after the abortion. Id. ¶ 29 (citing multiple studies).

Read literally, the Act requires a provider to evaluate the patient for any risk factors and disclose the specific complications associated with those risk factors, as described in a particular article in a journal in PubMed or the MJL. It does not suggest that providers can use their medical judgment to categorize risk factors and related complications or otherwise try to organize the different and very specific information in the literature in any reasonable way.

Thus, to comply with the Act even for the small sample of studies described above, Planned Parenthood would have to evaluate every patient for several related but nonetheless different risk factors relating to ambivalence—which can only be done by replicating as closely as possible the approach used in each particular study—and describe each of the different complications at each of the different time intervals for each of the factors, as well as disclosing any quantified risk rates. Such an evaluation would be highly complex and time-consuming for these few studies alone; it would surely be impossible for the potentially hundreds or even thousands of different risk factors described in the extensive literature covered by the Act.

Indeed, the picture gets even more complex—and the Act even more impossible to comply with, if taken literally—when risk factors that are made up of multiple characteristics (as opposed to one) are taken into account. Some articles treat as a "risk factor" a group or cluster of characteristics that is associated with a set of complications. For example, one study concludes that low self-esteem, low contraceptive knowledge, high alienation and delay in seeking the abortion are, collectively, related to long recovery times, psychopathology, and a large number of unpleasant body symptoms. Id. ¶ 30. Thus, if the Act is taken literally, Planned Parenthood would be in the impossible position of evaluating each woman not only for a range of related but non-identical risk factors relating to such topics as ambivalence, but also for different clusters of related characteristics that are treated as a single risk factor in the literature. See id. ¶ 31.

B. The Act is Impermissibly Vague

As explained above, read literally, the Act imposes requirements that are impossible to meet and thus the Act effectively bans abortions. If there are some sort of reasonable limitations on the Act's requirements, it is wholly unclear what those are. Thus, unless the Act is read literally (and thus impossible to satisfy), it forces physicians to "guess at its meaning and differ as to its application." Smith v. Goguen, 415 U.S. 566, 572 n.8 (1974). It therefore "trap[s] the innocent by not providing fair warning" and encourages "arbitrary and discriminatory enforcement." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972). This lack of clarity if the Act is not read literally raises particular concern because it implicates a constitutionally protected right and imposes "quasi-criminal" penalties in the form of significant civil and administrative penalties, including license revocation. See Colautti v. Franklin, 439 U.S. 379, 391 (1979) (review is more stringent where uncertainty "threatens to inhibit the exercise of constitutionally protected rights" (citations omitted)); Women's Med. Ctr. of Nw. Houston v. Bell, 248 F.3d 411, 422 (5th Cir. 2001) (defining as "quasi-criminal" a statute that imposed "significant civil and administrative penalties, including fines and license revocation" and holding that such statute must "define its terms with sufficient definiteness that ordinary people can understand what conduct is prohibited in a manner that does not encourage arbitrary and discriminatory enforcement." (quotation marks and citation omitted)).

Taken literally, the Act finds no parallel in any other medical context as, in standard medical practice—in Nebraska or elsewhere—healthcare providers do not engage in a scorched-earth literature search in order to stay informed about risk factors and complications for a procedure or treatment they provide; rather, they develop this knowledge from a variety of sources that synthesize and digest the information in the medical literature, as well as by reading

relevant articles in reliable journals in their area of practice and consulting with colleagues. Appelbaum Decl. ¶¶ 22-23; Eisenhauer Decl. ¶¶ 10-11. Nor do they evaluate patients for every potential risk factor published in the literature and disclose every associated complication; rather they exercise medical judgment to determine the risk factors and complications most likely to be material to the patient's medical decision-making. Appelbaum Decl. ¶¶ 18-21; Eisenhauer ¶¶ 12-13. Providers thus have no established framework that could assist them in figuring out the type of limitations that may be implicit in the Act's requirements, and, as a result, are left to guess at what those limitations are.

First, it is wholly unclear whether there are any boundaries on the materials that must be searched. For example, are there any date restrictions? As explained above, many of the articles relating to abortion that can be searched electronically through PubMed and Web of Science date back to the early 1900s. Do physicians have to search all these articles for potentially responsive information or can they rely only on the more recent publications? What about the types of journals that must be searched? Again, as explained, the MJL alone comprises more than 16,000 journal titles. Can providers limit their searches to journals in the relevant field (obstetrics and gynecology) or the most respected medical journals, or do they have to search each of the thousands of journals on PubMed and the MJL? And can they focus only on studies (as opposed to literature reviews or other types of articles)? What about articles only available in foreign languages? Indeed, PubMed alone comprises articles in more than forty languages—does a provider need to hire a translator in each of those languages? See Dickey Decl. ¶ 12; Meadows Decl. ¶ 10. Indeed, there is nothing in the Act to suggest which, if any, of these examples of potential limitations apply to the searching and gathering of the required materials.

Second, it is also hopelessly vague whether there any limitations on the risk factors and complications that must be part of the evaluation and discussion. See Dickey Decl. ¶ 13; Meadows Decl. ¶ 11-13. Above all, it is totally unclear whether providers can exercise their medical judgment in deciding what risk factors and complications to include. Must providers conduct the evaluations and make the disclosures without regard to the validity of the findings in the article or articles that linked the "risk factor" or "complication?" For example, what if the study's findings and/or conclusions have been rebutted and/or are disagreed with by the relevant medical community? As explained below, for example, there are articles encompassed by the Act (if taken literally) that find an association between abortion and breast cancer, for patients with certain risk factors—and yet this association has been flatly rejected by the national professional organizations with specialized expertise in cancer and reproductive health, as well as throughout the mainstream medical community. Meadows Decl. ¶¶ 16-21 (discussed in Part C(1)(a), infra). Similarly, what if the information that the Act would require to be disclosed (if taken literally) is based on studies of medical techniques and procedures from the 1970s, or in a developing country, and includes quantified risk rates that grossly overstate complication rates for patients receiving modern medical services in Nebraska? Id. ¶ 22-31 (discussed in Part C(1)(b)-(c), infra). And finally, what if the information that the Act would require to be disclosed (if taken literally) is based on studies with serious methodological problems that make it inappropriate to rely on their results? <u>Id.</u> ¶¶ 16-21, 31-38 (discussed in Part C(1)(d), <u>infra</u>).

Another category of questions unanswered by the Act, if it is not read literally, is whether Planned Parenthood must include information in the evaluation and discussion without regard to whether, in the physician's medical judgment, it would be applicable or material to the patient.

What if the complication associated with a risk factor is mild or transient, and/or extremely

unlikely to occur, and therefore unlikely to be material to the patient's medical decision-making? What if, in the physician's medical judgment, a study's conclusion that a risk factor increases the risk of a complication is inapplicable to the patient, notwithstanding the fact that the patient shares a risk factor addressed in the study? What if disclosing a laundry list of inapplicable or immaterial complications would only distract the patient from any material information, and thus would be detrimental to the patient's informed decision-making? See Meadows Decl. ¶ 13; see also Appelbaum Decl. ¶¶ 20-21, 31-34, 41-42.

Further, as explained above, studies discuss a range of risk factors that can be categorized under broad headings, such as "ambivalence," using very different methods and timing. Can physicians use their medical judgment to categorize risk factors and related complications and quantified risk rates, or otherwise try to organize the different and very specific information in the literature in any reasonable way? What about clusters of characteristics that only in combination make up a single risk factor in a study? Are providers required to look for all those possible permutations and combinations in every patient? See Dickey Decl. ¶ 14.

In short, the overarching question completely unanswered by the Act is whether Planned Parenthood and its practitioners can be liable in any of these circumstances for exercising their medical judgment in determining what information to include in their evaluation of and discussion with the patient. Again, nothing in the Act suggests how any of these questions—among many others—would be resolved.

Consequently, Planned Parenthood and its providers will have to guess how to comply with the Act and will never know for certain whether they have properly evaluated their patients or made the required disclosures. Similarly, because of the Act's lack of standards on which to judge compliance, defendants will be free to interpret its provisions inconsistently or perhaps

discriminatorily. As such, the Act's vagueness will impose a profound chilling effect on Planned Parenthood's ability to perform abortions in Nebraska. See Grayned, 408 U.S. at 109 ("[u]ncertain meanings inevitably lead citizens to 'steer far wider of the unlawful zone . . . than if the boundaries of the forbidden areas were clearly marked'" (quoting Baggett v. Bullitt, 377 U.S. 360, 372 (1964))).

C. The Act is Unconstitutional Because It Requires Planned Parenthood to Convey Information that is Untruthful, Misleading, and Not Relevant to the Patient's Decision

Unless physicians can exercise their best medical judgment to determine what risk factors and complications should be evaluated for and discussed, the Act violates physicians' First Amendment free speech rights and patients' Fourteenth Amendment liberty rights because it compels speech that is untruthful and misleading. Casey establishes that only "truthful and not misleading" statements may be compelled under the First and Fourteenth Amendments. 505 U.S. at 882, 884; see also Rounds, 530 F.3d at 735. Further, the statements must be "relevant" to the woman's decision; Casey establishes that a statement may be relevant if it is aimed at ensuring "a decision that is mature and informed." 505 U.S. at 883.

(1) the untruthful, misleading, and not relevant information required by the Act

The Act requires Planned Parenthood to give, and patients to receive, untruthful, misleading, and not relevant information. Absent ability to exercise medical judgment, the Act requires Planned Parenthood to evaluate the patient for any risk factor that has been published in any article encompassed by the Act as being statistically associated with a complication or complications associated with abortion, and inform the patient of the associated complications and any quantified risk rates—regardless of whether the information has been disproven, or is based on data from a developing country with a vastly different medical and social context, or on

medical techniques as they were practiced forty years ago, or on articles whose methodology has been recognized by experts as too flawed to be reliable, or for any of a variety of other reasons would be untrue and misleading to provide to patients as part of the informed consent process. Disclosure of such false and misleading information, which cannot be relevant to patient decision-making, cannot constitutionally be compelled.

(a) breast cancer

For example, one article that appears to be covered by the Act, if taken literally, finds that for women without a prior full-term pregnancy, having an abortion in the first trimester of pregnancy (which is the gestational age at which the vast majority of Planned Parenthood's abortion services are provided) the risk of breast cancer goes up nearly two-and-a-half times. Meadows Decl. ¶ 16 (citing M.C. Pike et al., Oral Contraceptive Use and Early Abortion as Risk Factors For Breast Cancer in Young Women, 43 Brit. J. Cancer 72 (1981)). The national professional organizations with specialized expertise in cancer and reproductive health have flatly rejected any association between abortion and breast cancer. Id. ¶¶ 18-21 (citing National Cancer Institute, Summary Report: Early Reproductive Events and Breast Cancer Workshop, http://www.cancer.gov/cancertopics/ere-workshop-report (last visited Jun. 23, 2010) ("Induced abortion is not associated with an increase in breast cancer risk."); American Cancer Society, Is Abortion Linked to Breast Cancer?, http://www.cancer.org/docroot/CRI/CRI 2 5x.asp?dt=5 (follow "Is Abortion Linked to Breast Cancer?" hyperlink) (last visited Jun. 23, 2010) ("At this time, the scientific evidence does not support the notion that abortion of any kind raises the risk of breast cancer."); American College of Obstetrics and Gynecology ("ACOG") Committee on Gynecologic Practice, ACOG Committee Opinion No. 434: Induced Abortion and Breast Cancer Risk, 113 Obstetrics & Gynecology 1417 (2009) ("Early studies of the relationship between prior

induced abortion and breast cancer risk were methodologically flawed. More rigorous recent studies demonstrate no causal relationship between induced abortion and a subsequent increase in breast cancer risk.")). These leading professional organizations further recognized that the methodology used in the Pike article and other early studies of abortion and breast cancer is flawed and unreliable. <u>Id.</u> Thus, the purported two-and-a-half-times increase in breast cancer risk for certain abortion patients is false and misleading information that Planned Parenthood cannot constitutionally be forced to provide.

(b) studies from developing countries

Another article that appears to trigger a requirement to provide false and misleading information (if the Act is taken literally) studied abortion services in Nigeria and concluded, among other things, that if a woman is less than twenty years old at the time of the abortion she has a 31.2% risk of heavy bleeding (described as "so much bleeding you thought you might die") within a day of the procedure. Id. ¶ 23 (citing Tisha M. Mitsunaga et al., *Risk Factors for Complications of Induced Abortions in Nigeria*, 14 J. Women's Health 515, 522 (2005)). It also concluded that if a woman is Protestant, she has a 29.7% risk of heavy bleeding, and if Catholic, 24.7%; whereas if a woman is a member of certain other religious groups her risk of this complication would be far lower. Id.; Mitsunaga, supra, at 523.

It would be untrue, and extremely misleading, for Planned Parenthood to inform every 19-year-old patient that she has a 31.2% chance of hemorrhage (the more precise term for the bleeding described in the study), when in actuality her risk of hemorrhage would be far, far less. Meadows Decl. ¶ 24. And it would be equally untrue and misleading to inform every Protestant or Catholic patient that her risk of hemorrhage is 29.7% or 24.7%, respectively. Id. ¶ 23. Yet this is exactly what the Act appears to require, if physicians are not permitted to exercise medical

judgment to determine what associations are reliable and likely to be applicable to their patients. It is not surprising that these risk rates would grossly overstate the actual hemorrhage risk of Nebraska patients, given that (among other factors) the article states that abortion is largely illegal in Nigeria, and there is no indication that the abortions at issue were provided under sanitary conditions by providers with appropriate technique, training, and equipment. Id. ¶ 25; Mitsunaga, supra, at 516; see also Appelbaum Decl. ¶¶ 39-41. Further, the article states that the association between membership in certain religions and the increased hemorrhage rate is likely because in Nigeria membership in these religions is a proxy for a variable such as socioeconomic status or lack of support in finding a safe abortion provider. The social context of being Protestant or Catholic is very different in Nebraska, and clearly members of these religions are not at a heightened risk for hemorrhage. Meadows Decl. ¶ 25; Mitsunaga, supra, at 521; see also Appelbaum Decl. ¶ 40 ("It would be obviously misleading to require automatic disclosure to Nebraska patients of complication rates associated with a particular risk factor in patients receiving a medical service in a developing country, in which medical services, baseline health and nutrition levels, and social context may all be very different from what is found in Nebraska.").

(c) out-of-date medical information and techniques

If taken literally, the Act also appears to require Planned Parenthood to provide information based on studies of abortion as it was practiced in the early 1970s. One such study concluded that if a woman has an abortion after the first trimester, she has an 8.3% risk of cervical laceration, hemorrhage, repeat curettage, or other complications. Meadows Decl. ¶ 26 (citing David T.Y. Liu et al., *Comparative Morbidity after Vaginal Termination with regard to Parity and Gestational Stage*, 28 Brit. J. Clinical Prac. 170, 170 (1974)). It would be misleading

and untrue to provide this complication rate to a patient today who seeks an abortion after the first trimester, as the provision of second-trimester abortions has developed and improved significantly since the 1970s, and the patient's actual risk of such complications would be far lower. Id. ¶ 27; see also Appelbaum Decl. ¶ 38 ("[T]he fact that the state of medical knowledge is constantly developing and evolving means that procedures and medications do not stay the same, and nor do risk factors and complications Thus, requiring evaluations and disclosures based on out-of-date articles would lead to patients getting poor-quality information that in some cases will be highly misleading").

Similarly, an article that examined abortions in Yugoslavia in the early 1970s found that having previously carried a pregnancy to term is a risk factor for complications from abortion, resulting in a 5.5% chance of a complication requiring hospital admission. Meadows Decl. ¶ 29 (citing Mark Cheng et al., *Complications Following Induced Abortion by Vacuum Aspiration*, 8 Studies Fam. Plan. 125, 127 (1977)). The article also found that a prior miscarriage increased complication rates to 20.3%. Id.; Cheng, supra, at 127-28. Again, it would be untrue and misleading to tell patients in Nebraska in 2010 that they would incur these complication rates as a result of an abortion if they previously carried a pregnancy to term or had a miscarriage; these complication rates are extremely high, and bear no resemblance to current complication rates in the United States. Meadows Decl. ¶ 30.

(d) articles the American Psychological Association has found unreliable

If taken literally, the Act also appears to require disclosures based on articles finding associations between various risk factors and negative psychological experiences after abortion that have been identified by the American Psychological Association Task Force on Mental Health and Abortion ("APA Task Force") as having serious methodological problems that make

it inappropriate to rely on their results. Meadows Decl. ¶ 31. The APA Task Force (which in addition to its obvious expertise in psychological issues also has expertise in study design and methodology) criticized this group of studies for their retrospective methodology, in which potential risk factors were assessed only after the abortion, at the same time that the patient's psychological experiences after the abortion were assessed. Id. ¶ 32 (citing Brenda Major et al., Report of the APA Task Force on Mental Health and Abortion 74 (2008), available at http://www.apa.org/pi/women/programs/abortion/mental-health.pdf). The APA Task Force concluded that these studies "have serious methodological problems that negate their ability to answer questions about psychological experiences following abortion." Id.; Major, supra, at 74.

One such article concluded, among other things, that not being employed full time, more years of education, or a history of divorce were variously associated with higher rates after abortion of symptoms of post-traumatic stress disorder, disruption in cognitive schemas, and/or self-reported stress. Meadows Decl. ¶ 38 (citing Vincent M. Rue et al., *Induced Abortion and Traumatic Stress*, 10 Med. Sci. Monitor SR5, SR14 (2004)). The study examined only women who had abortions, an average of 10.6 years after the abortion, and asked these women to fill out questionnaires about their history at the time of the abortion and their subsequent mental health—which, as the APA Task Force recognized, is not a reliable methodology. <u>Id.</u> at SR15; Major, <u>supra</u>, at 74, 83.

It would be untrue, and very misleading, for Planned Parenthood to have to disclose to every patient who is divorced, or has "more" years of education, or is not employed full-time, that these factors put her at higher risk of symptoms of post-traumatic stress disorder, disruption in cognitive schemas, and/or stress if she chooses to have an abortion, based on a study that has

obvious methodological flaws, and which the APA Task Force has rejected as unreliable. Meadows Decl. ¶ 34; Major, supra, at 74, 83.

Another article rejected as unreliable by the APA Task Force concluded, among other things, that if a woman has consulted with her sexual partner and he supports her abortion decision, this factor is associated with less favorable long-term adjustment after the abortion. In this study, risk factors and complications were assessed based on questionnaires the women filled out an average of nine years after the abortion—which again, as the APA Task Force recognized, is not a reliable methodology. Meadows Decl. ¶ 35 (citing Jeanne Parr Lemkau, *Post-Abortion Adjustment of Health Care Professionals in Training*, 61 Am. J. Orthopsychiatry 92, 95 (1991)); Major, supra, at 74, 83, 87.

Again, it would be false and misleading for Planned Parenthood to disclose this information to every patient who has consulted with her partner about her abortion decision and received his support. If anything, having a partner's support in her abortion decision is generally understood to be helpful to a woman, not harmful. Meadows Decl. ¶ 36.

Finally, it is worth noting that even with regard to those studies of risk factors for negative psychological experiences after abortion that had far sounder methodologies than the studies discussed above, the APA Task Force concluded that:

[M]any of the same factors shown to be associated with more negative post-abortion psychological experiences also predict more negative reactions to other types of stressful life events, including child-birth For instance, low perceived social support and low self-esteem are risk factors for postpartum depression. Most risk factors are not uniquely predictive of psychological experiences following abortion. Women characterized by one or more such risk factors might be equally (or more) likely to experience negative psychological reactions if they pursued an alternative course of action (motherhood or adoption).

<u>Id.</u> ¶ 37; Major, <u>supra</u>, at 92 (emphasis added) (citations omitted).

Even in the absence of specific methodological problems that make a study's findings unreliable, it would be misleading to inform a patient that, because she has a particular risk factor (such as low self-esteem), if she has an abortion she will be at an increased risk of a negative psychological reaction. If this type of information is given in the context of an informed consent conversation, patients will naturally understand that they can avoid this risk by choosing not to have an abortion; after all, the purpose of informed consent is to enable patients to make informed medical decisions. Meadows Decl. ¶ 38; Appelbaum Decl. ¶ 17. And yet, as the APA Task Force recognizes, women with this type of "risk factor" can *not* avoid this risk by choosing not to have the abortion—carrying to term may expose them to the same or greater risk of a negative psychological reaction as having an abortion.

In short, if the Act is taken literally, and understood to prohibit physicians from exercising medical judgment in determining what risk factors, complications, and risk rates are valid and may be appropriately applied to their patients, it requires Planned Parenthood to provide information to its patients that is untrue, misleading, and in no way relevant to its patients' informed decision-making. Such disclosures cannot constitutionally be compelled.

It is not surprising that the Act, if read literally, requires healthcare providers to provide their patients with information that is false and misleading. This problem is inherent in the structure of the Act (if it is understood to deprive physicians of their ability to exercise judgment as to what information is reliable and applicable to their patients). The Act appears to treat peer review and p-values as if they could protect patients from false and misleading information, but this vastly overstates their role. While both are intended to provide some check on the quality of evidence entering the medical literature, neither provides anything close to complete protection,

and neither provides any information about the patients to whom a study's findings can reasonably be applied, much less whether information has become out-of-date.

Peer review is an imperfect system at best. There are significant differences in the quality of peer review among journals, and while some journals have rigorous peer review, others do not. Appelbaum Decl. ¶ 45. Further, there is no requirement that peer-reviewed journals reject articles that receive negative responses from the reviewers; this is a discretionary determination by the journal editor. Id. In addition, part of the reason that medical knowledge is constantly evolving is that many findings that are published even in the best journals (much less in the broader range of peer-reviewed journals) are subsequently disproven, and/or subsequently understood to be methodologically suspect in ways that were not understood at the time. Id. ¶

Similarly, the fact that an association is published with a p-value of less than .05 is no guarantee that it is valid, or replicable, or otherwise reasonably likely to be a reliable source of patient information. P-values are very limited in what they purport to measure; a p-value of less than .05 simply means that the study's authors claim there is a less than 5% probability that the statistical association at issue is due to chance. Id. ¶ 48. P-values provide no information about a study's methodological soundness. Id. ¶ 49. This is critical; if a study's methodology is poor, its p-value is meaningless as an indicator of the validity of the study's finding. Id. P-values also provide no indication of the magnitude or clinical relevance of what is being measured, only its statistical validity. Id. ¶ 51. And obviously, p-values provide no information as to whether a study's results may reasonably be applied to a different population than the one that was studied. Id. ¶ 52.

D. The Act's Application to Out-of-State Providers Violates the Due Process Clause and the Commerce Clause

The Act violates the rights of providers, including Planned Parenthood and its staff, who provide abortions outside the state of Nebraska and who do so in compliance with their domestic state law. Although it flies in the face of clear Supreme Court precedent and our federalist constitutional structure to do so, the Act attempts to export Nebraska state law concerning the provision of abortion services to every out-of-state physician who advertises in Nebraska for abortion services performed out-of-state. Act, § 10(4). What is more, this provision is not even limited to out-of-state physicians providing abortions to *Nebraska* residents: If the words of the Act are taken literally, any Iowa provider who advertises in Nebraska for abortion services, and then provides an abortion to an Iowa resident who has never once stepped foot outside the state (let alone into Nebraska), must comply with Nebraska law in the performance of that abortion. Even absent such a broad reading, however, the Act, by its terms, attempts to restrict conduct that takes place wholly out of state and is lawful where it occurs. Thus, by virtue of its extraterritorial reach, the Act violates Due Process and the Commerce Clause, not to mention the most basic principles of federalism and comity, and must be enjoined.

In <u>Bigelow v. Virginia</u>, 421 U.S. 809 (1975), the Supreme Court vacated the conviction under a Virginia statute of a Virginia newspaper for publishing an advertisement for abortion services in New York. At the time of the prosecution, abortion was legal in New York. The Court noted that the "services advertised in appellant's newspaper were legally provided in New York at that time. *The Virginia Legislature could not have regulated the advertiser's activity in New York, and obviously could not have proscribed the activity in that State*" 421 U.S. at 822-23 (emphasis added) (citations omitted). The Court went on to explain that

[a] State does not acquire power or supervision over the internal affairs of another State merely because the welfare and health of its own citizens may be affected when they travel to that State [I]t may not, under the guise of exercising internal police powers, bar a citizen of another State from disseminating information about an activity that is legal in that State.

<u>Id.</u> at 824-25. The Court concluded that a state law prohibiting the advertisement of an activity that is lawful where it occurs violates the First Amendment.

Recent cases confirm that this fundamental principle applies to attempts to regulate outof-state conduct. See State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 421-22 (2003), (finding due process violated by state court's imposition of punitive damages for out-of-state conduct that was legal where it occurred); BMW of N. Am., Inc. v. Gore, 517 U.S. 559, 571-73, nn.16 & 19 (1996) (same, stating that a state can neither punish a defendant for conduct that was lawful in the state where it occurred nor impose sanctions to deter such conduct); N.Y. Life Ins. Co. v. Head, 234 U.S. 149, 161 (1914) (finding Due Process clause would be violated if Missouri law invalidated an agreement made in conformity with the laws of another state because "it would be impossible to permit the statutes of Missouri to operate beyond the jurisdiction of that State . . . without throwing down the constitutional barriers by which all the States are restricted within the orbits of their lawful authority and upon the preservation of which the Government under the Constitution depends. This is so obviously the necessary result of the Constitution that it has rarely been called in question and hence authorities directly dealing with it do not abound."); cf. Healy v. Beer Inst., Inc., 491 U.S. 324, 336-37 (1989) (finding that state statute violated Commerce Clause because it had the practical effect of controlling conduct occurring beyond the boundaries of that state); Nat'l Foreign Trade Council v. Natsios, 181 F.3d 38, 69 (1st Cir. 1999), aff'd, 530 U.S. 363 (2000) (noting that state may not regulate conduct occurring outside its borders and finding that law which did so violated Foreign Commerce Clause).

Likewise, the extraterritorial application of the Act violates the Commerce Clause. U.S. Const. art. 1, § 8, cl. 3. "[A] statute has extraterritorial reach when it necessarily requires out-of-state commerce to be conducted according to in-state terms." Cotto Waxo Co. v. Williams, 46

F.3d 790, 794 (8th Cir. 1995). The Commerce Clause provides: "The Congress shall have Power

... [t]o regulate Commerce ... among the several States" Id. at 793. It has long been understood that "this affirmative grant of authority to Congress also encompasses an implicit or 'dormant' limitation on the authority of the States to enact legislation affecting interstate commerce." Healy, 491 U.S. at 326 n.1. On this basis, the United States Supreme Court has invalidated laws that—like the Act—have the "practical effect" of regulating commerce outside that state's borders. See, e.g., id. at 337-38 (invalidating Connecticut beer price affirmation statute that resulted in that state controlling the beer prices in neighboring states); Edgar v. MITE Corp., 457 U.S. 624, 642-43 (1982) (invalidating Illinois Business Takeover Act that had "sweeping extraterritorial effect"); see also cases cited in Healy, 491 U.S. at 331-36. Indeed, citing Healy, the Eighth Circuit has held that:

Under the Commerce Clause, a state regulation is *per se invalid* when it has an "extraterritorial reach," that is, when the statute has the practical effect of controlling conduct beyond the boundaries of the state. The Commerce Clause precludes application of a state statute to commerce that takes place wholly outside of the state's borders.

<u>Cotto Waxo</u>, 46 F.3d at 793 (emphasis added) (citations omitted). The Act, which by its terms applies extraterritorially, is plainly—indeed, *per se*—unconstitutional under this analysis.

The Act violates these fundamental principles of our constitutional structure by attempting to legislate the (otherwise lawful) medical practices of providers *outside of Nebraska* merely because they have advertised in Nebraska. As this Court recognized more than sixty years ago, "Nebraska's Legislature is not the arbiter of the internal morality or the domestic

policy of any state other than Nebraska." Remick Music Corp. v. Interstate Hotel Co. of Nebraska, 58 F.Supp. 523, 539 (D.C. Neb. 1944) (holding Nebraska anti-trust law "must be denied any extraterritorial effect"). The cases cited above make clear that this attempt to enforce Nebraska law extraterritorially is simply impermissible.

II. PLANNED PARENTHOOD AND ITS PATIENTS WILL SUFFER IRREPARABLE HARM IF THE ACT IS NOT ENJOINED

In the absence of relief from this Court, Planned Parenthood and its providers are faced with an untenable choice: cease providing all abortion services in Nebraska, or undertake reasonable efforts to comply with the Act, which—given the impossibility of literal compliance or the vagueness of the Act's requirements—would still leave them at constant risk of significant penalties, including revocation of their facility license and their medical staff's professional licenses; and countless civil lawsuits, where providers would be presumptively liable for untold damages, costs, and attorneys' fees. Moreover, efforts to comply will cause Planned Parenthood and its staff to suffer ongoing violations of their constitutional rights and those of their patients, as well as significant financial harm. Each option entails irreparable injury to providers and their patients. See Dickey Decl. ¶ 3, 15-16; see also Blanchard Decl. ¶ 27 (explaining that would be "exorbitant[ly]" expensive to try to comply with the Act).

The first—ceasing to provide abortions in Nebraska—would deny providers' patients their constitutional right to choose to terminate a pregnancy. No further showing of injury is necessary. The potential denial of the constitutional right to choose abortion supports a determination of irreparable harm. See Planned Parenthood of Minnnesota, Inc. v. Citizens for Cmty. Action, 558 F.2d 861, 867 (8th Cir. 1977) (plaintiffs' showing of interference "with the exercise of its constitutional rights and the rights of its patients supports a finding of irreparable injury"); Planned Parenthood Ass'n of Cincinnati, Inc. v. City of Cincinnati, 822 F.2d 1390,

1400 (6th Cir. 1987) ("[T]here is potential irreparable injury in the form of a violation of constitutional rights."); Deerfield Med. Ctr. v. City of Deerfield Beach, 661 F.2d 328, 338 (5th Cir. 1981) (finding of irreparable injury is mandated where constitutional right to privacy is being threatened or impaired); Doe v. Charleston Area Med. Ctr., Inc., 529 F.2d 638, 644 (4th Cir. 1975) (the "denial under color of law of the right to abort . . . constitutes irreparable injury"); Carhart v. Stenberg, 972 F. Supp. 507, 531 (D. Neb. 1997) ("It is well established that a statute that 'interfere[s] with the exercise of [abortion providers'] constitutional rights and the rights of [their] patients supports a finding of irreparable injury." (citation omitted)); Pilgrim Med. Group v. New Jersey State Bd. of Med. Exam'rs, 613 F. Supp. 837, 848-49 (D.N.J. 1985) (the injury from the loss of the right to decide to have an abortion "is as irreparable as an that can be imagined: not only does it flow from the deprivation of constitutional rights, but it also creates a situation which is irreversible and not compensable"); Planned Parenthood of Kansas and Mid-Missouri, Inc v. Drummond, No. 07-4164-CV-C-ODS, 2007 WL 2811407, at *9 (W.D.Mo. Sept. 24, 2007) ("Plaintiffs' showing that the Act will interfere with the exercise of their 'constitutional rights and the rights of [their] patients' constitutes irreparable harm." (citation omitted)).

The second—engaging in reasonable efforts to comply—would also impose irreparable harm to providers and their patients. Because the Act imposes impossible (or, at a minimum, unknowable) requirements on physicians, even reasonable efforts to comply would leave Planned Parenthood and its providers open to the real and constant threat of significant and quasi-criminal penalties. These penalties include loss of their clinic license; loss of their staff's professional licenses; and a civil lawsuit every time an abortion is performed in which providers could be presumptively liable for untold damages, costs, and attorneys fees based solely on a

claim of failure to disclose a single supposed complication and/or risk rate under the Act—exposure that could well put providers out of business. See Bell, 248 F.3d at 422 (regulations that carry "significant civil and administrative penalties, including fines and license revocation . . . can be characterized as quasi-criminal"). In the context of restrictions on abortion, the threat of such penalties establishes irreparable harm. See Planned Parenthood of Cent. New Jersey v. Verniero, 41 F. Supp. 2d 478, 504 (D.N.J. 1998) ("The Act also threatens irreparable injury to plaintiff physicians and Planned Parenthood because they may face license revocation and heavy fines for performing constitutionally-permissible abortions."); see also Women's Med. Prof'l Corp. v. Taft, 114 F. Supp. 2d 664, 704, 705 n.55 (S.D. Ohio 2000) (including threat of civil liability in the form of lawsuits against the physician in finding irreparable harm).

If there are limitations on the Act, it is wholly unclear what those are. Enforcement of the vague law will infringe Planned Parenthood's and its practitioners' constitutional right to due process and therefore poses a substantial threat of irreparable injury. See Bell, 248 F.3d at 422 (affirming district court's finding that vague law poses a substantial threat of irreparable injury absent an injunction); see also Reprod. Health Servs. of Planned Parenthood of the St. Louis Region, Inc. v. Nixon, 428 F.3d 1139, 1144 (8th Cir. 2005) (district court did not abuse its discretion in concluding that potentially vague law threatened irreparable injury).

Moreover, compliance obviously entails a significant expenditure of time and resources, at immediate financial harm to providers. See Citizens for Cmty. Action, 558 F.2d at 866-67 (finding that immediate financial harm is irreparable injury); see also A Woman's Choice-East Side Women's Clinic v. Newman, 904 F. Supp. 1434, 1475 n.28 (S.D. Ind. 1995) (noting that "financial harm" to the clinics providing abortions "would be irreparable"). Compliance also would inevitably entail giving patients information that is either untruthful, misleading, or

otherwise not relevant to the patient's decision, and therefore would violate providers' First Amendment rights. The loss of First Amendment constitutional "freedoms . . . unquestionably constitutes irreparable injury." Elrod v. Burns, 427 U.S. 347, 373 (1976); see also Kirkeby v. Furness, 52 F.3d 772, 775 (8th Cir. 1995) (citing Elrod). Finally, patients will obviously be harmed by having to undergo a highly personal and intrusive evaluation (including numerous psychosocial factors) that is not necessary for her medical care, and by being forced to receive numerous disclosures of supposed complications that are misleading, untrue, and/or not relevant, and may ultimately be detrimental to her ability to make informed medical decisions, in violation of their Fourteenth Amendment liberty and privacy rights.

III. THE BALANCE OF HARM TIPS DECIDEDLY IN PLANNED PARENTHOOD'S FAVOR

The issuance of a temporary injunction poses little, if any, likelihood of irreparable harm to Defendants. An injunction would merely serve to maintain the status quo in Nebraska, where providers are already required to comply with both statutory and common law informed consent requirements, and there has been no showing that such laws have failed to adequately protect the interests of women seeking abortions in Nebraska. Moreover, Defendants clearly have no valid interest in enforcing an unconstitutional law. ACLU v. Johnson, 194 F.3d 1149, 1163 (10th Cir. 1999) ("[T]hreatened injury to [constitutional rights] outweighs whatever damage the preliminary injunction may cause Defendants' inability to enforce what appears to be an unconstitutional statute." (citation omitted)); Saint v. Nebraska Sch. Activities Ass'n, 684 F. Supp. 626, 628 (D.Neb. 1988) (negligible harm to defendants in losing the ability to enforce likely unconstitutional regulations); cf. Cincinnati, 822 F.2d at 1400 ("[T]here is a likelihood that the Ordinance will be found unconstitutional; it is therefore questionable whether the City has any 'valid' interest in enforcing the Ordinance.").

On the other hand, the denial of an injunction would deprive Planned Parenthood, its staff, and their patients of their constitutional rights. Either women will be unable to obtain abortion services in Nebraska and will suffer significant harm as a result, or Planned Parenthood and its staff will face significant penalties, financial harm, and violations of their constitutional rights and those of their patients, even if Planned Parenthood engages in reasonable efforts to comply with the Act. Thus, the harm to Planned Parenthood, its staff, and its patients if the Act is not enjoined far exceeds any harm to Defendants resulting from the issuance of a temporary injunction.

IV. GRANTING TEMPORARY INJUNCTIVE RELIEF SERVES THE PUBLIC INTEREST

Finally, granting an injunction in this case will serve the public interest. The public interest is served by an injunction that protects constitutional rights. See Cincinnati, 822 F.2d at 1400 ("[T]he public is certainly interested in the prevention of enforcement of ordinances which may be unconstitutional."); Martin-Marietta Corp. v. Bendix Corp., 690 F.2d 558, 568 (6th Cir. 1982) ("It is in the public interest not to perpetuate the unconstitutional application of a statute."); Reinert v. Haas, 585 F. Supp. 477, 481 (S.D. Iowa 1984) (public interest "is always well served by protecting the constitutional rights of all its members").

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiff's Motion for Preliminary Injunction and Temporary Restraining Order.

Dated: June 28, 2010 BY: PLANNED PARENTHOOD OF THE

HEARTLAND, Plaintiff

BY: /s/ Andrea D. Snowden

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CERTIFICATE OF SERVICE

I, Andrea D. Snowden, am one of the attorneys of record for Plaintiff and hereby certify that on the 28th day of June, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system and hand delivered a copy to the following:

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